

WHAT IS CLAIMED IS:

1 1. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;
3 at least one source of at least one therapeutic capable agent associated with the
4 scaffold and configured to release the therapeutic capable agent within the patient's body at a
5 controlled rate; and
6 a rate-controlling element layer covering at least a portion of the source and
7 including at least one therapeutic capable agent and providing for an initial relatively more
8 rapid release of the at least one therapeutic capable agent therapeutic from the rate-controlling
9 element layer as well as a sustained, controlled release of the at least one therapeutic capable
10 agent from the source.

1 2. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;
3 at least one source of at least one therapeutic capable agent associated with the
4 scaffold ; and
5 a rate-controlling element disposed adjacent at least a portion of the source
6 and being configured to control the release of the therapeutic capable agent in the patient's
7 body at an initial rate and at a subsequent rate relatively slower than the initial rate.

1 3. A device as in Claim 1 or 2 wherein the rate-controlling element
2 covers the source.

1 4. A device as in Claim 1 or 2 wherein the rate-controlling element
2 covers only a portion of the source.

1 5. A device as in Claim 1 or 2 wherein the source comprises a reservoir.

1 6. A device as in Claim 5 wherein the reservoir is at least partially
2 disposed over the expandable structure.

1 7. A device as in Claim 1 or 2 wherein the scaffold comprises a tissue
2 facing and a luminal facing surface.

1 8. A device as in Claim 7 wherein the reservoir is disposed adjacent the
2 luminal facing surface.

1 9. A device as in Claim 7 wherein the reservoir is disposed adjacent the
2 tissue facing surface.

1 10. A device for intracorporeal use within a patient's body, comprising:
2 a radially expansible implantable scaffold having a plurality of regions
3 exhibiting different mechanical profiles during the expansion of the scaffold and including
4 relatively lower and relatively higher mechanical profiles; and
5 a source of at least one therapeutic capable agent comprising a plurality of
6 segments and disposed adjacent at least a portion of the scaffold.

1 11. A device as in Claim 10 wherein the segments are disposed adjacent
2 the relatively lower mechanical profile regions.

1 12. A device as in Claim 10 wherein the segments are disposed adjacent
2 the relatively higher mechanical profile regions.

1 13. A device as in Claim 10 wherein the segments are disposed adjacent
2 only the regions that do not undergo substantial bending, flexing, stretching, or compressing
3 upon the expansion of the scaffold.

1 14. A device as in Claim 10 wherein the segments are disposed adjacent
2 only the regions that do not undergo more than about 5% of bending, flexing, stretching, or
3 compressing upon the expansion of the scaffold.

1 15. A device as in Claim 10 wherein the segments are disposed adjacent
2 only the regions that undergo substantial bending, flexing, stretching, compressing upon the
3 expansion of the scaffold.

1 16. A device as in Claim 10 wherein the areas exhibiting relatively higher
2 mechanical profile are configured to be in a direct flow of body fluids flowing through the
3 intracorporeal body.

1 17. A device as in Claim 10, 13, or 16 further comprising a rate-controlling
2 element disposed adjacent the scaffold.

1 18. A device as in Claim 17 wherein the rate-controlling element is
2 disposed adjacent at least a portion of the source.

1 19. A device as in Claim 17 wherein the rate-controlling element is formed
2 from a nonporous material.

1 20. A device as in Claim 18 wherein the rate-controlling element has a
2 variable thickness.

1 21. A device as in Claim 20 wherein the rate-controlling element has a
2 greater thickness adjacent scaffold regions having relatively higher mechanical profile.

1 22. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;
3 at least one source of at least one therapeutic capable agent associated with at
4 least a portion of the scaffold and configured to release the therapeutic capable agent within
5 the patient's body; and
6 a rate-controlling element disposed adjacent at least a portion of the source
7 and including at least one disruption sufficiently large to permit material transport to or from
8 the source.

1 23. A device as in Claim 22 wherein the at least one disruption is an
2 aperture.

1 24. A device as in Claim 22 or 23 wherein the at least one disruption is
2 preformed.

1 25. A device as in Claim 22 or 23 wherein the at least one disruption is
2 formed in the patient's body.

1 26. A device as in Claim 22 or 23 wherein the transport comprises at least
2 one of transport of native fluids to the source or of the therapeutic capable agent from the
3 source.

1 27. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;
3 at least one source of at least one therapeutic capable agent associated with at
4 least a portion of the scaffold and configured to release the therapeutic capable agent within
5 the patient's body; and

6 a rate-controlling element disposed adjacent at least a portion of the source
7 and being configured to mechanically change upon application of mechanical stress or strain.

1 28. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;
3 at least one source of at least one therapeutic capable agent associated with at
4 least a portion of the scaffold and configured to release the therapeutic capable agent within
5 the patient's body; and

6 a rate-controlling element disposed adjacent at least a portion of the source
7 and which undergoes a mechanical change upon being implanted in the patient's body.

1 29. A device as in Claim 27 or 28 wherein the mechanical change is one of
2 mechanical fracture.

1 30. A device as in Claim 27 or 28 wherein the mechanical change is one of
2 change in surface characteristic.

1 31. A device as in Claim 27 or 28 wherein the mechanical change is one of
2 change in porosity.

1 32. A device as in Claim 27 wherein the mechanical stress or strain is
2 applied upon the bending of the scaffold.

1 33. A device as in Claim 27 wherein the mechanical stress or strain is
2 applied upon the expansion of the scaffold.

1 34. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;
3 at least one source of at least one therapeutic capable agent associated with at
4 least a portion of the scaffold and configured to release the therapeutic capable agent within
5 the patient's body; and

6 a swellable rate-controlling element disposed adjacent at least a portion of the
7 source.

1 35. A device as in Claim 34 wherein the rate-controlling element swells
2 upon exposure to the intracorporeal environment.

- 1 36. A device as in Claim 35 wherein the rate-controlling element is
2 configured to release the therapeutic capable agent from the source.
- 1 37. A device as in any one of Claims 1, 10, 22, or 27 wherein the device
2 comprises a stent.
- 1 38. A device as in Claim 37 wherein the stent comprises metallic material.
- 1 39. A device as in Claim 37 wherein the stent comprises polymeric
2 material.
- 1 40. A device as in Claim 39 wherein the stent comprises a degradable
2 material.
- 1 41. A device as in Claim 39 wherein the stent comprises a non-degradable
2 material.
- 1 42. A device as in Claim 37 wherein the device is balloon-expandable.
- 1 43. A device as in Claim 37 wherein the device is self-expandable.
- 1 44. A device as in Claim 37 wherein the source comprises a matrix.
- 1 45. A device as in Claim 44 wherein the matrix includes a matrix material.
- 1 46. A device as in any one of Claims 1, 10, 22, 27, or 37 wherein the rate-
2 controlling element is formed from a nonporous material.
- 1 47. A device as in Claim 46 wherein the porosity of the rate-controlling
2 element changes upon implanting in the patient's body.
- 1 48. A device as in Claim 1, 10, 22, 27, or 37 wherein the rate-controlling
2 element is formed from a porous material.
- 1 49. A device as in Claim 46 or 47 wherein the rate-controlling element
2 comprises a parylene polymer or copolymer.
- 1 50. A device as in Claim 48 wherein the parylene comprises parylene C.

1 51. A device as in Claim 46 wherein the rate-controlling element becomes
2 at least partially porous upon expansion of the scaffold.

1 52. A device as in Claim 46 or 48 wherein a rate of release of the
2 therapeutic capable agent from the device in an unexpanded state in the patient's body is
3 different than that in an expanded state.

1 53. A luminal prosthesis comprising:
2 a scaffold which is implantable within a body lumen;
3 a substance-containing reservoir positioned over at least a portion of a surface
4 of the scaffold; and
5 a rate-controlling element layer covering at least a portion of the substance-
6 containing reservoir, the rate-controlling element layer having the substance dispersed therein
7 and providing for an initial rapid release of the substance from the rate-controlling element
8 layer as well as a sustained, controlled release of the substance from the reservoir.

1 54. A luminal prosthesis comprising:
2 a scaffold which is implantable in a body lumen, said scaffold being radially
3 expansible and having regions which undergo greater and lesser mechanical stress or strain
4 during radial expansion; and
5 a substance-containing reservoir or layer comprising individual portions which
6 are preferentially positioned over the regions which undergo lesser stress or strain.

1 55. A luminal prosthesis as in Claim 54, wherein the substance-containing
2 layer is positioned only on those portions of the scaffold that do not substantially bend,
3 stretch, or compress when the scaffold is expanded.

1 56. A luminal prosthesis as in Claim 54, further comprising a rate-
2 controlling element layer formed over at least a portion of the scaffold.

1 57. A luminal prosthesis as in Claim 56, wherein the rate-controlling
2 element layer is thicker over regions of greater mechanical profile.

1 58. A luminal prosthesis comprising:
2 a scaffold which is implantable within a body lumen;

3 a substance-containing reservoir positioned over at least a portion of a surface
4 of the scaffold; and

5 a rate-controlling element layer covering at least a portion of the substance-
6 containing reservoir, the rate-controlling element layer having at least one preformed aperture
7 which is sufficiently large to permit the transport of body fluids to the substance-containing
8 reservoir and/or the release of substance from the reservoir.

1 59. A luminal prosthesis comprising:

2 a scaffold which is implantable within a body lumen;

3 a substance-containing reservoir positioned over at least a portion of a surface
4 of the scaffold, and

5 a rate-controlling element layer covering at least a portion of the substance
6 containing reservoir, the rate-controlling element layer being configured to fracture when
7 stressed by substantially bending, expanding, stretching, or compressing of the scaffold.

1 60. A luminal prosthesis comprising:

2 a scaffold which is implantable within a body lumen;

3 a substance-containing reservoir positioned over at least a portion of a surface
4 of the scaffold; and

5 a rate-controlling element layer covering at least a portion of the substance
6 containing reservoir, the rate-controlling element layer being configured to swell to permit
7 release of substance from the reservoir when exposed to a luminal environment.

1 61. A luminal prosthesis comprising:

2 a scaffold which is implantable within a body lumen;

3 a substance-containing reservoir positioned over at least a portion of a surface
4 of the scaffold; and

5 a rate-controlling element positioned over at least a portion of the surface of
6 the scaffold and covering less than all of the substance containing reservoir.

1 62. A luminal prosthesis as in any of Claims 53 through 61, wherein the
2 luminal prosthesis comprises a metal stent.

1 63. A luminal prosthesis as in Claim 62, wherein the metal stent is balloon
2 expandable.

- 1 64. A luminal prosthesis as in Claim 62, wherein the metal stent is self-
2 expanding.
- 1 65. A luminal prosthesis as in any of Claims 53 through 61 wherein the
2 substance-containing reservoir comprises a matrix layer including the substance dispersed in
3 a matrix material.
- 1 66. A luminal prosthesis as in Claim 65, wherein the substance and the
2 matrix material have been vapor deposited on the scaffold.
- 1 67. A luminal prosthesis as in any of Claim 53 through 61, wherein the
2 substance-containing layer consists essentially of a homogeneous layer of the substance.
- 1 68. A luminal prosthesis as in Claim 67, wherein the substance has been
2 vapor deposited on the scaffold.
- 1 69. A luminal prosthesis as in any of Claims 53 through 61, wherein the
2 scaffold comprises structural elements having rectangular cross-sections defining four
3 orthogonal surfaces, wherein the drug is positioned on fewer than all of the surfaces.
- 1 70. A luminal prosthesis as in any of Claims 53 through 61, wherein the
2 rate-controlling element is porous.
- 1 71. A luminal prosthesis as in any of Claim 53 through 61, wherein the
2 rate-controlling element is nonporous.
- 1 72. A luminal prosthesis as in any of Claims 53 through 61 further
2 comprising a base layer over at least a portion of the scaffold and at least a portion of the
3 substance-containing layer.
- 1 73. A luminal prosthesis as in any of Claims 53 through 61, wherein the
2 rate-controlling element layer comprises a parylene polymer or copolymer.
- 1 74. A luminal prosthesis as in Claim 73, wherein the parylene has been
2 vapor deposited over the scaffold or a portion thereof.
- 1 75. A luminal prosthesis as in Claim 73, wherein the parylene comprises
2 parylene C.

- 1 76. A luminal prosthesis as in Claim 73, wherein the parylene is
2 nonporous.
- 1 77. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;
3 at least one source of at least one therapeutic capable agent having a degree of
4 crystallinity less than about 90 % and associated with the scaffold and configured to release
5 the therapeutic capable agent within the patient's body ; and
6 a rate-controlling element disposed adjacent at least a portion of the source
7 and being configured to control the release of the therapeutic capable agent to the patient's
8 body.
- 1 78. A device as in Claim 77 wherein the therapeutic capable agent has a
2 degree of crystallinity less than about 50 %.
- 1 79. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;
3 at least one source of at least one therapeutic capable agent associated with the
4 scaffold and configured to release the therapeutic capable agent at a targeted tissue site within
5 the patient's body; and
6 a rate-controlling element disposed adjacent at least a portion of the source
7 and being configured to effectuate a therapeutic capable agent flux density of about 1.71×10^{-14}
8 $\text{ug}/(\text{cm}^2\text{s})$ to about $1.71 \times 10^{-8} \text{ug}/(\text{cm}^2\text{s})$.
- 1 80. A device for as in Claim 79 wherein the flux density ranges from about
2 $1.71 \times 10^{-14} \text{ug}/(\text{cm}^2\text{s})$ to about $3.43 \times 10^{-9} \text{ug}/(\text{cm}^2\text{s})$.
- 1 81. A device for as in Claim 79 wherein the flux density ranges from about
2 $8.57 \times 10^{-12} \text{ug}/(\text{cm}^2\text{s})$ to about $3.43 \times 10^{-9} \text{ug}/(\text{cm}^2\text{s})$.
- 1 82. A device for as in Claim 79 wherein the flux density ranges from about
2 $1.71 \times 10^{-11} \text{ug}/(\text{cm}^2\text{s})$ to about $1.03 \times 10^{-9} \text{ug}/(\text{cm}^2\text{s})$.
- 1 83. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;

3 at least one source of at least one therapeutic capable agent associated with the
 4 scaffold and configured to release the therapeutic capable agent at a targeted tissue site within
 5 the patient's body; and
 6 a rate-controlling element disposed adjacent at least a portion of the source
 7 and being configured to control the release of the therapeutic capable agent in the patient's
 8 body, the device having a residual stress in an unexpanded state less than about 10%.

1 84. A device for as in Claim 83 wherein the residual stress is less than
 2 about 5 %.

1 85. A device for as in Claim 83 wherein the residual stress is less than
 2 about 1%.

1 86. A device for as in Claim 83 wherein the residual stress is less than
 2 about 0.5%.

1 87. A method for making a device for intracorporeal use, comprising:
 2 providing an implantable structure having a first residual stress and including
 3 a scaffold; and
 4 at least one source of at least one therapeutic capable agent associated with the
 5 scaffold and configured to release the therapeutic capable agent at a targeted tissue site within
 6 the patient's body;
 7 changing the structure residual stress to a second residual stress;
 8 disposing a rate-controlling element adjacent at least a portion of the source
 9 and being configured to control the release of the therapeutic capable agent in the patient's
 10 body.

1 88. A method as in Claim 87 wherein the changing step comprises
 2 reducing the residual stress.

1 89. A method as in Claim 87 wherein the changing step comprises
 2 exposing the structure to ultrasound energy for a period of time.

1 90. A method as in Claim 87 wherein the changing step comprises
 2 exposing the structure to vibrational energy for a period of time.

1 91. A method as in Claim 87 wherein the changing step comprises heating
2 the structure to a first temperature for a period of time.

1 92. A method as in Claim 91 wherein the first temperature is less than the
2 melting point of the therapeutic capable agent.

1 93. A method as in Claim 91 wherein the first temperature is about the
2 same as the melting point of the therapeutic capable agent.

1 94. A method as in Claim 91 wherein the at least one therapeutic capable
2 agent comprises a plurality of therapeutic capable agents and the first temperature is about the
3 same as the melting point of the therapeutic capable agent with the lowest melting point.

1 95. A method as in Claim 91 wherein the first temperature is more than the
2 melting point of the therapeutic capable agent.

1 96. A method as in Claim 91 wherein the at least one therapeutic capable
2 agent comprises a plurality of therapeutic capable agents and the first temperature is more
3 than the melting point of the therapeutic capable agent with the lowest melting point.

1 97. A method as in Claim 87, 88, 89, 90, 91, 92, 93, or 95 wherein the
2 changing step is performed before the disposing step.

1 98. A method as in Claim 87, 88, 89, 90, 91, 92, 93, or 95 wherein the
2 changing step is performed after the disposing.

1 99. A method as in Claim 87 wherein the changing step comprises heating
2 the structure to a second temperature for a period of time and is performed after the disposing
3 step.

1 100. A method as in Claim 99 wherein the heating of the structure to a
2 second temperature is performed under vacuum.

1 101. A method as in Claim 99 wherein the heating of the structure to a
2 second temperature is performed in the absence of oxygen.

1 102. A method as in Claim 98 wherein the second temperature is less than
2 the glass transition temperature of the rate-controlling element.

1 103. A method as in Claim 98 wherein the first temperature is about the
2 glass transition temperature of the rate-controlling element.

1 104. A method as in Claim 98 wherein the first temperature is more than the
2 glass transition temperature of the rate-controlling element.

1 105. A method as in Claim 87 wherein the changing step comprises the step
2 of both Claims 91 and 99.

1 106. A device for intracorporeal use within a patient's body, comprising:
2 an implantable scaffold;
3 at least one source of at least one therapeutic capable agent associated with
4 the scaffold and configured to release the therapeutic capable agent within the patient's body;
5 and
6 a rate-controlling element layer covering at least a portion of the source and
7 being formed from a non-porous material.

1 107. A device as in Claim 106, wherein the non-porous material comprises
2 parylene.

1 108. A device as in Claim 106, wherein the nonporous material becomes at
2 least partially porous when exposed to conditions in the patient's body.

1 109. A device as in claim 106, wherein the rate-controlling element
2 becomes disrupted when exposed to conditions in the patient's body.

1 110. A device as in Claim 106, wherein the rate-controlling element
2 includes a therapeutic capable agent.

1 111. A device as in Claim 110, wherein the therapeutic capable agent in the
2 rate controlling element is the same as the therapeutic capable agent in the source.

1 112. A device as in claim 106, wherein the nonporous material is selected
2 from the group consisting of plasma deposited polymers, sputtered materials, evaporated
3 materials, electroplated metals, electroplated alloys, glow discharge coatings, polyethylenes,
4 polyurethanes, silicone rubber, cellulose, and parylene.